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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,079	Applicant(s) FARIABI, SEPEHR	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-50, 53, 54, 56-76, and 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 5,891,193) in view of Mayer (US 5,824,077). Robinson meets the claim language where the stent of Robinson has a relaxed state where it will not self expand, but it is capable of being bent (permanently deformed) to form the stent; see column 5, lines 31-51. Therefore, the stent is plastically deformable and could be expanded to a state where there would be no bends in the wires; this unbent expanded diameter reads on the “diameter suitable to hold open the coronary artery” as claimed. Particularly, the size of a coronary vessel varies depending upon the particular patient being treated, and thus, the size of the device as claimed is met by Robinson’s device which is also balloon expandable to an unbent form of the segments (33). The unbent form and the other forms thereof are the size of some individuals. Additionally, self-expansion depends upon how the device is used and how it is biased. For this reason, the Examiner maintains that the claim language is read on by Robinson’s device as it is disclosed.

The claimed alloy of the claimed stent is extremely similar to the material (MP35N from Carpenter Technology) of Robinson’s device; see Robinson on column 5,

lines 34-38 and see the present specification on page 13. However, Robinson fails to disclose an alloy containing iron, tungsten, or manganese as claimed.

Mayer teaches that MP35N was known to be closely related and interchangeable with ELGILOY that does contain iron; see column 3, line 60 to column 4, line 3. Therefore, it is the Examiner's position that it would have been clearly obvious to an ordinary artisan to utilize ELGILOY as the alloy of Robinson for the reason it was chosen over MP35N by Mayer. Alternatively, it would have been obvious to encase the MP35N stent of Robinson with ELGILOY in order to improve the mechanical properties or for the same reasons that Mayer chose ELGILOY over MP35N as the casing material; see the abstract of Mayer

With regard to the new limitations of claim 37, due to the fact that permanent bends can be put in the wires of Robinson, the Examiner asserts that there is inherently a state of compression that would plastically deform the stent of Robinson since the low profile configuration has no limit and includes placing a plastically deforming amount of pressure on the stent to compress it.

With regard to claim 50, Robinson fails to disclose the percentage of nickel claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize a 2% nickel alloy because Applicants have not disclosed that doing so provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well as a

stent. Therefore, it would have been an obvious matter of design choice to modify Robinson to obtain the invention as specified in the claims.

With regard to claim 59, Applicants are directed to Figure 2 of Robinson.

With regard to claims 60 and 61, the aspect ratio claimed is considered be to be broad because it is associated with the modifier “about.” For this reason and upon inspection of Robinson’s figures, the Examiner determined that the claimed aspect ratios claimed are met by Robinson; see Figure 2, which is read on by the present claim language for claim 60 and see Figure 4 for the ratio of two to one.

With regard to claims 54, 62-71, and 75, the electrochemical polishing step is considered to be a product-by-process limitation. Since the degree that this step is performed is not specified, the Examiner posits that it would not result in a product that is different that that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if different, is only slightly different. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

With regard to claims 70 and 71, the aspect ratio claimed is considered be to be broad because it is associated with the modifier “about.” For this reason and upon inspection of Robinson’s figures, the Examiner determined that the aspect ratios claimed are met by Robinson.

With regard to claims 68, 69, and 76, the cold working or age hardening step is considered to be a product-by-process limitation. Since the degree that this step is performed is not specified, the Examiner posits that it would not result in a product that

is different than that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if different, is only slightly different. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

With regard to claims 84 and 85, the step of cutting voids from a member is considered to be a product-by-process limitation. Since Robinson also discloses a stent with voids therein, the Examiner posits that process of cutting would not result in a product that is different than that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if different, is only slightly different. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

Claims 51 and 52 are rejected under 35 U.S.C. 103 as being unpatentable over Robinson et al (US 5,891,193) and Mayer (US 5,824,077) as applied against claim 37 above, and further in view of Hillstead (US 4,856,516) or Tower (US 5,217,483). Robinson et al as modified by Mayer meets the claim language except for the transverse diameter of about 0.003 inches. However, Hillstead (see column 3, lines 43-45) and Tower (see column 2, lines 34-43) both disclose stents constructed of wires having a diameter (which would be the transverse diameter) of about 0.003 inches. Hence, it is the Examiner's position that it would have been obvious to construct the Robinson device with wires of about 0.003 inches for the same reasons that Hillstead and Tower do the same and in order to have a low profile for the stent.

Claims 55 and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 5,891,193) and Mayer (US 5,824,077) as applied against claim 37 above, and further in view of Bokros (US 4,300,244). Robinson fails to disclose the use of a biocompatible coating thereon. However, Bokros teaches that it was known to coat similar cardiovascular implants with biocompatible coating in order to render them more biocompatible; see column 2, lines 16-24. Therefore, it is the Examiner's position that it would have been obvious to coat the Robinson device with a biocompatible coating to make it more biocompatible.

Response to Arguments

Applicant's arguments filed August 18, 2008 have been fully considered but they are not persuasive.

In the response, the Applicant argues that there is no suggestion that plastic deformation can occur within a coronary artery; see page 13 of the response. However, this argument is based upon where the device is intended to be utilized and not on any particular structure. One could reasonably utilize the Robinson device in a coronary artery where the device is sized to expand as described. That is, the stent could be plastically deformable and could be expanded to a state where there would be no bends in the wires; this unbent expanded diameter reads on the "diameter suitable to hold open the coronary artery" as claimed.

Furthermore, since substantially the same material composition is utilized by Robinson as that claimed, the claimed property of plastic deformation would be inherent thereto; see MPEP 2112 that is incorporated herein by reference. Therefore, the

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burden of showing that the claimed alloys, within the entire range encompassed by the claims, have plastic deformation properties distinct and unobvious to those of Robinson rests with the Applicant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Preblich whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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